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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,640	06/23/2003	Akira Fujishima	2003_0867	6104

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EXAMINER

MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/600,640

Applicant(s)

FUJISHIMA ET AL.

Examiner

Patricia L. Morris

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1, 2 and 4 are under consideration in this application.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102 (a), (e) and/or (f) as being anticipated by Barberich et al, Nohara et al and Kato et al for the reasons set forth in the previous Office action.

Again, Barberich et al. disclose the instant compound and salts thereof. Note section 0013 wherein the instant compound can be produced in crystalline form.

Kato et al. and Nohara et al. specifically teach the compound in crystalline form which embraces the two optical isomer forms. Note column 3. lines 23-25 therein of Kato et al. or the first compound in column 10, line 5, of Nohara et al. Kato et al. teach that the compounds exist in two types of isomers. Note column 6, lines 37-45, therein. Hence, each of the isomers are deemed to be anticipated therefrom.

Contra to applicants' arguments in the instant response filed March 22, 2004, where a reference describes a sufficiently limited genus of a number of compounds closely related to another in structure, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Kato et al teach the compounds exist in two types of isomers. Accordingly, in the instant case, since the formula has an asymmetric carbon, one merely has to select from two possible optical isomers to arrive at the claimed invention.

The factual situation here is well within the "Petering doctrine": In re Petering et al., 49 CCPA 993, 301 F.2d 676, 133 USPQ 275 (1962). There the court affirmed a 102(b) rejection on the ground that the prior art, while it did not expressly name applicants' claimed compounds, did describe such a limited class of only twenty compounds "that one skilled in this art would at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here" (133 USPQ at 280). Here we do not have anywhere near twenty possible compounds within the limited class described by the references.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Barberich et al., Nohara et al. and Kato et al. in view of Chemical & Engineering News, Feb. 2003, US Pharmacopia, 1995, pp 1843-1844 and Concise Encyclopedia Chemistry, page 872-873 (1993) for the reasons set forth in the previous Office action..

Again, Barberich et al. teach the crystal forms of the instant known S-isomer. Kato et al. and Nohara et al. teach the crystalline racemate that includes the two types of isomers and which retain pharmaceutical activity. Chemical & Engineering News, US Pharmacopia and Concise Encyclopedia teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-a-vis* the known compounds are suggested by the references. It would appear obvious to one skilled in the art in view of the references that the instant compound would exist in different isomeric crystalline forms. No unexpected or unobvious properties are noted.

Contra to applicants's arguments in the instant response, it well known that isomers and their racemates have different activities. With respect to one isomer being essentially inactive, it will be seen that in the third paragraph from the end of *In re Adamson*, 125 USPQ 133, the court

states that the affidavit therein shows the laevo-isomer to be about twice as active as the racemate and the dextro-isomer to be virtually inactive, as antispasmodics. The court found that the prior art reasonably suggested the result shown in the affidavit. In the penultimate paragraph of the decision, the court comments that "in establishing that fact experimentally, appellants have done no more than is suggested by the prior art and have ascertained no more than what would be expected by one skilled in the art, i.e., the activities are different. Moreover, applicants have failed to provide any objective evidence.

Applicants now rely on references that are not of record in the record to support that the instant isomer cannot be crystallized. This is nonpersuasive because the references of record support that the instant compound can be crystallized. Further, the examiner cannot read Japanese so the articles in Japanese cannot be considered.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 1, 2 and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,462,058 in view of Chemical & Engineering News, US Pharmacopia and Concise Encyclopedia Chemistry.

Again, 058' disclose crystal forms of the R isomer of the instant compound. The ancillary references teach that the mere existence of further polymorphs of compounds is not in itself regarded as unexpected. Hence, patentable distinction is not seen.

Claims 1, 2 and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 10 of U.S. Patent No. 4,628,098 in view of Baberich et al., Chemical & Engineering News, US Pharmacopia and Concise Encyclopedia Chemistry..

Again, the crystalline racemate of the instant optically active isomers. Baberich et al. teach that the racemic mixture is potentially separable. Note page 2, section 0013. The ancillary references teach that different crystalline forms are not unexpected. Hence, patentable distinction is not seen.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on March 22, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,608,092 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Priority***

Again, applicants are requested to update the status of the parent application on page 1 of the specification. Cooperation herein is appreciated.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

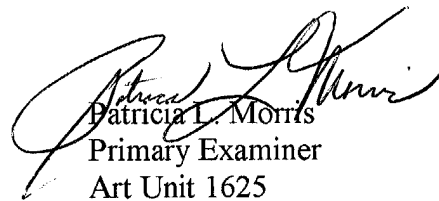
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris  
Primary Examiner  
Art Unit 1625

plm  
June 8, 2004